JUL 2 3 2002

K021687

510(k) Summary of Safety and Effectiveness

June 28, 2002

Submitter

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 530-7500
Fax: (503) 526-4200

Contact: Mr. Don M. Abbey, Vice President, Quality Systems

Device Name

Trade Name: Micropaq™ vital signs monitor, models 402 and 404
Common Name: Cardiac Monitor
Classification Name: Cardiac Monitor (Reference, 21CFR870.2300, April 1, 2001). The Micropaq model 404 also contains a Pulse Oximetry (SpO_2) channel (Reference, 21CFR870.2700, April 1, 2001).
Classification: Class II

Predicate Device

Device Description

The Micropaq is a patient wearable device that provides real time monitoring and display of ECG and SpO2. The Micropaq is powered by a rechargeable battery and has a liquid crystal display (LCD) that displays both waveforms and numerics. The Micropaq communicates with Welch Allyn Protocol's Acuity® central station through a wireless local area network (WLAN) operating in the ISM 2.4 GHz band. The communication link is bi-directional, providing monitoring at the Acuity central station and remote control of the Micropaq from the Acuity central station.

Indications for Use

The Micropaq monitor is intended to be used by clinicians for single or multiparameter vital signs monitoring of ambulatory and non-ambulatory pediatric and adult patients in health care facilities. It is also intended for patient transport. Micropaq is intended to operate with an Acuity® central station through wireless communication over Welch Allyn's FlexNet™ network. FlexNet connects multiple devices through hardwired Ethernet networks and Wireless Local Area Networks (WLANs) to an Acuity® central station. If the Micropaq is moved out of range or loses communication with the FlexNet network, it continues to monitor the patient, display patient data, and generate local patient alarms or alert messages.

- The ECG channel is intended for five-lead ECG monitoring.
- The Pulse Oximetry channel is intended for continuous noninvasive monitoring of functional oxygen saturation of arteriolar hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor).

The most likely locations for patients monitored by this device are step-down units, telemetry departments, general med/surg floors, emergency departments, and in-hospital transport. This device is available for sale only upon the order of a physician or licensed health care professional.

Technological Comparison to the Predicate Device

The Micropaq 400 series monitors are substantially equivalent to the Micropaq 400 series monitors cleared for market under 510(k) submission number K002725. The SpO2 channel in the model 404 is substantially equivalent to the SpO2 channel in the Nellcor Puritan Bennett, Inc.N-595 Pulse Oximeter cleared for market under 510(k) number K019821

Summary of Performance Testing

The Micropaq and associated accessories have been tested and found to comply with the recognized, national and international, performance, safety, and electromagnetic compatibility standards for medical devices and product specifications listed in the Micropaq labeling.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of Welch Allyn Protocol's product development procedures. Welch Allyn Protocol's Quality System conforms to 21CFR820 and certified by TÜV Product Service to ISO 9001 and EN460011.

Conclusions
As stated above and in the previous 510(k) submission number K002725, Welch Allyn Protocol's conclusion is that the Micropaq vital signs monitor and WLAN connection to the Acuity central station is safe, effective, complies with the appropriate medical device standards; and is substantially equivalent to the Criticare System, Inc. MPT® 2.4 Multiple Parameter Telemetry and RF link to their Vital View™ 2.4 Central Station, and the SpO2 channel in the Nellcor Puritan Bennett, Inc. N-595 Pulse Oximeter cleared for market under 510(k) submission number K019821.

This *510(k) Summary of Safety and Effectiveness* may be copied and submitted to interested parties as required by 21CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Mr. Donald M. Abbey
Vice President, Quality Systems
Welch Allyn Protocol, Incorporated
8500 SW Creekside Place
Beaverton, Oregon 97008-7107

Re: K021681
Trade/Device Name: Micropaq, Models 402 and 404
Regulation Number: 870.2300 and 870.2700
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm) and Oximeter
Regulatory Class: II
Product Code: DRT and DQA
Dated: June 28, 2002
Received: July 1, 2002

Dear Mr. Abbey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant:
Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 530-7500
Fax: (503) 526-4200

510(k) Number: K021681

Device Name: Micropaq™ vital signs monitor, models 402 and 404

Indications for Use:
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(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021681